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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | | 10577607 |
| | Filing Date | | 2006-04-27 |
| | First Named Inventor | W. Charles O'Neill | |
| | Art Unit | 1619 | |
| | Examiner Name | Tigabu Kassa | |
| | Attorney Docket Number | 050508-1400 | |

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| 1 | O'NEILL, W. CHARLES et al. Treatment with pyrophosphate inhibits uremic vascular calcification. Kidney International 2011; 79: 512-517. USA. | <input type="checkbox"/> |
| 2 | RUSSEL RGG et al. Pyrophosphate and diphosphates in calcium metabolism and their possible role in renal failure. Archives of Internal Medicine 1969; 124: 571-575. Switzerland. | <input type="checkbox"/> |
| 3 | MEYER JL. Can biological calcification occur in the presence of pyrophosphate? Archives of Biochemistry and Biophysics 1984; 231: 1-8. USA. | <input type="checkbox"/> |
| 4 | FRANCIS MD et al. Diphosphonates inhibit formation of calcium phosphate crystals in vitro and pathological calcification in vivo. Science 1969; 165: 1264-1266. USA. | <input type="checkbox"/> |
| 5 | TERKELTAUB, RA. Inorganic pyrophosphate generation and disposition in pathophysiology. American Journal of Physiology Cell Physiology 2001; 281: C1-C11. USA. | <input type="checkbox"/> |
| 6 | RUTSCH F et al. PC-1 nucleoside triphosphate pyrophosphohydrolase deficiency in idiopathic infantile arterial calcification. American Journal of Pathology 2001; 158: 543-554. USA. | <input type="checkbox"/> |
| 7 | GODING JW et al. Ecto-phosphodiesterase/pyrophosphate of lymphocytes and non-lymphoid cells; structure and function of the PC-1 family. Immunological Reviews 1998; 161: 11-26. Denmark. | <input type="checkbox"/> |
| 8 | O'NEILL WC et al. Plasma pyrophosphate and vascular calcification in chronic kidney disease. Nephrology Dialysis Transplantation 2010; 25: 187-191. England. | <input type="checkbox"/> |
| 9 | LOMASHVILI KA et al. Upregulation of alkaline phosphatase and pyrophosphate hydrolysis; potential mechanism for uremic vascular clarification. Kidney International 2008; 73: 1024-1030. USA. | <input type="checkbox"/> |
| 10 | PRICE PA et al. Artery calcification in uremic rats is increased by a low protein diet and prevented by treatment with ibandronate. Kidney International 2006; 70: 1577-1583. USA. | <input type="checkbox"/> |
| 11 | LOMASHVILI KA et al. Effect of bisphosphates on vascular calcification and bone metabolism in experimental renal failure. Kidney International 2009; 75: 617-625. USA. | <input type="checkbox"/> |

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| 12 | MURSHED M et al. Unique coexpression in osteoblasts of broadly expressed genes accounts for the spatial restriction of ECM mineralization to bone. Genes & Development 2005; 19: 1093-1104. USA. | <input type="checkbox"/> |
| 13 | FEDDE KN et al. Alkaline phosphatase knock-out mice recapitulate the metabolic and skeletal defects of infantile hypophosphatasia. Journal of Bone and Mineral Research 1999; 14: 2015-2026. USA. | <input type="checkbox"/> |
| 14 | NEVEN E et al. Endochondral bone formation is involved in media calcification in rats and in men. Kidney International 2007; 72: 574-581. USA. | <input type="checkbox"/> |
| 15 | HENLEY C et al. 1,25 Dihydroxyvitamin D3 but not cinacalcet HCl (Sensipar/Mimpara) treatment mediates aortic calcification in a rat model of secondary hyperparathyroidism. Nephrology Dialysis Transplantation 2005; 20: 1370-1377. England. | <input type="checkbox"/> |
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| 18 | YOKOZAWA T et al. Animal model of adenine-induced chronic renal failure in rats. Nephron 1986; 44: 230-234. Japan. | <input type="checkbox"/> |
| 19 | OKADA H et al. Reversibility of adenine-induced renal failure in rats. Clinical and Experimental Nephrology 199; 3: 82-88. Japan. | <input type="checkbox"/> |
| 20 | MOOREHEAD W et al. 2-amino-2-methyl-1-propanol as the alkalizing agent in an improved continuous-flow cresolphthalein complexone procedure for calcium in serum. Clinical Chemistry 1974; 20: 1458-1460. USA. | <input type="checkbox"/> |
| 21 | MALLUCHE H et al. A new semiautomatic method for quantitative static and dynamic bone histology. Calcified Tissue International 1982; 34:439-448. USA. | <input type="checkbox"/> |
| 22 | MANAKA RC et al. A program package for quantitative analysis of histologic structure and remodeling dynamics of bone. Computer Programs in Biomedicine 1981; 13: 191-202. USA. | <input type="checkbox"/> |

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| 23 | COGAN EB et al., A robotics-based automated assay for inorganic and organic phosphates, Anal Biochem 1999; 271: 29-35. USA | <input type="checkbox"/> |
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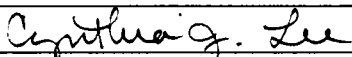
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- ☐ See attached certification statement.
- ☐ The fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☒ A certification statement is not submitted herewith.

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|------------|---|---------------------|------------|
| Signature |  | Date (YYYY-MM-DD) | 2011-11-28 |
| Name/Print | Cynthia J. Lee | Registration Number | 46,033 |

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